COMMITTEE ON HUMAN RESEARCH INITIAL SHORT-FORM APPLICATION

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CO-P.I. (Name & Degree) Neal Benowitz, M.D.	University Title Prof. of Medicine	_Dept. Medicine
Mailing Address Bldg 30, 5th Floor, SFGH, (Campus) 1001 Potrero Ave., SF, 94110	Phone Number 821-8324	SUBMISSION
PROJECT TITLE The Relationship of Tobacco Exposure	to Semen Biomarkers	DATE 5 July 1990

INSTRUCTIONS: Please submit five (5) identical, collated sets of the following:
THIS COMPLETED SHORT-FORM (both sides)
ALL CONSENT FORMS/INFORMATION SHEETS
ALL ATTACHMENTS (i.e., questionnaires, interview guides, support letters)

PLEASE NOTE: See PART V of the UCSF Guidelines for Research Involving Human Subjects (October 1987) for detailed information and directions on all of the above. It takes approximately 4 to 6 weeks to complete the review process of a CHR Initial Short-Form Application.

1. STUDY AIM, BACKGROUND, AND DESIGN The purpose of this study is to expand a larger, agoing study to evaluate the relationship between active and passive smoke exposure to semen biourkers. The larger study, the Men's Reproductive Health Study (MRHS), is being jointly conducted the Calif. Dept. of Hith. Serv. (CDHS), Kaiser Div. of Research, U.C., Davis and Lawrence vermore Natl. Laboratory. The MRHS is a prospective, 5 year study (currently in year 3) that will allow mormal couples at risk for pregnancy to determine the relationship between semen qualty, reproductive outcomes and a number of environmental exposures. Women collect daily urine for x months which is assayed for hCG. Their male partners provide two semen samples by masturbation at a saliva sample. Both complete an extensive baseline interview. Is component of the MRHS is to assay semen and saliva samples for nicotine and cotinine, then alwate the relationship between these measures of exposure and semen biomarkers.

2. SUBJECT POPULATION: INCLUSION/EXCLUSION CRITERIA, USE OF

SPECIAL SUBJECT GROUPS, AND METHODS OF ACCESS

iser Division of Research is screening 6,000 subscribers to the Santa Clara Kaiser medical facily to identify eligible women who are willing to collect daily urine samples for six months. igibility criteria for women are: (1) age 18 to 39, (2) no unprotected intercourse for greater an 3 months with current partner, (3) neither she nor her partner have been sterilized, (4) not ing oral contraceptives or an intrauterine device, (5) not amenorrheic or hyterectomized, and) not pregant in the past six months. All male partners of participating women will be contacted telephone for recruitment.

3. PROCEDURES TO BE DONE FOR PURPOSES OF THE STUDY

liva samples and semen samples will be assayed by gas chromatography-mass spectroscopy for cotine and cotinine concentrations.

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CHR SHORT-FORM

4. RISKS: POTENTIAL RISKS, INCLUDING POSSIBLE LOSS OF CONFIDENTIALITY, AND DISCOMFORTS TO SUBJECTS. METHODS OF MINIMIZING THESE RISKS

ere are no known physical risks to participating subjects and the procedures are not uncomfortable ere may be some psychological or social harm to subjects if the confidentiality of their particition was compromised. To prevent this, all samples and data received will be marked only with man subject numbers (HSN), no personal identifying information. The code is maintained by the iser Division of Research. Database created will be identified only by the HSN and will contain personal identifiers.

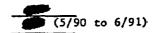
5. BENEFITS: POTENTIAL DIRECT BENEFITS TO SUBJECTS AND GENERAL
BENEFITS TO SUBJECT GROUP, MEDICAL SCIENCE AND/OR SOCIETY

are is no direct benefit to subjects. Medical science and society may benefit with insight into
a effect of active and passive tobacco smoke exposure on measures of male reproductive function.

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6. CONSENT PROCESS AND DOCUMENTATION can subjects approval for the MRES was received from the Kaiser Permanente Institutional Review and on December 19, 1989. A copy of the approval and the consent form is attached.

7. NUMBER OF SUBJECTS TO BE ENROLLED PER YEAR:
TOTAL FOR STUDY:



8.	WILL THIS STUDY BE FUNDED? X Yes No Pending	
	FUNDING SOURCE:Federal X_Other	
•	AGENCY/SPONSOR: Tobacco-Related Research Program	
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9. EXPEDITED REVIEW CATEGORY NUMBER 2.11 (from PART V-B of the UCSF Guidelines for Research Involving Human Subjects, October 1987)

10. PRINCIPAL-INVESTIGATOR'S SIGNATURE Daird Cemack

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